ISO 17025

General Requirements for the Competence of Testing and Calibration Laboratories

2000 RMAP Training

Representatives of the 17025 Working Group

Michael Dynia, State of Connecticut
L.F. Eason, State of North Carolina
Ken Fraley, State of Oklahoma
Georgia Harris, NIST
Carol Hockert, State of Minnesota
Kelley Larson, State of Arizona
Diane Lee, NIST
Erin McNicholas, State of Oregon
Danny Newcombe, State of Maine
Joe Rothleder, State of California
Jose Torres, Puerto Rico

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Objectives of this Training?

- Laboratory Operation and Documentation System
- History of Quality Standards for the State Labs
- What's *NEW*?
- What's the *IMPACT*?
- What's *NEXT*?
- Case Studies
- Q&A

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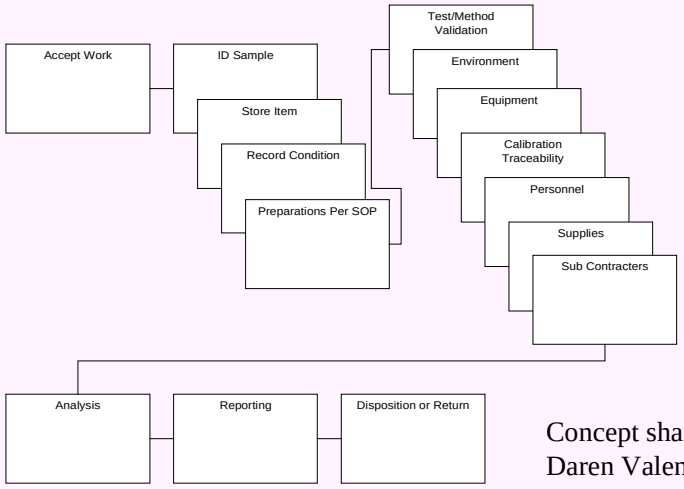
Objectives and outline for the day.

Laboratory Operation

- Work Flow referenced to ISO 17025



Concept shared by
Daren Valentine, A2LA

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Documentation System

- Documents of intent (Say what you do…)
  - Policy
  - Procedures
  - Documented Quality System
  - Established Program
    - Schedule
    - Procedures
  - Arrangement - how is the lab documented to accomplish its function
- Evidence of what was done (Did you do what you said?)
  - Records
  - Certificates

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History of Quality Standards for the State Laboratories

- Pre-1986, no formal documented program
- ISO Guide 25 - 1982 (HB 143, 1986)
  - HB 143, Appendix D Quality System
  - HB 145: Mil-Std 45662
- ISO 9000 Task Force
  - ISO Guide 25 - 1990, ISO 9001
  - ANSI/NCSL Z 540-1-1994, Part I and II (Guide 25, Mil-Std 45662A)
- 1996/1997 Updates
  - Technical Criteria for Mass, Volume (HB 143, NVLAP 150-2)
  - NIST Handbook 143, 1996/1997
  - NIST IR 5802, Template Quality Manual
  - Draft Administrative Procedures
  - July 1, 2001 given as 5-year deadline

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Update of ISO/IEC Guide 25 - 1990

- 1994: CASCO WG 10 formed
- 1995: Update started
- Objectives: Clarify relationship to ISO 9001/2, cover a broader scope
- 1997: CASCO given authority to develop International Standards
- Decision: Guide 25 → International Standard ISO 17025
- DIS 17025 July 1998
- FDIS 17025:1999 (E) October 1999

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CASCO = Conformity Assessment Committee (ISO Council Committee CASCO)
WG = Working Group
DIS = Draft International Standards
FDIS = Final Draft International Standards

1970's = NVLAP and A2LA started
1977 = ILAC established International Laboratory Accreditation Council
1978 = WG developed first ISO Guide 25
1982 = First revision of ISO Guide 25 (the one adopted in HB 143 in 1986)
1987 = ISO 9000 series came about
1990 = ISO Guide 25 updated again (3rd Edition)
1994 = ISO 9000 series updated

US Representation ANSI/ICAC (Int'l Conformity Assessment Committee)
James L. Cigler, NVLAP Chair
Peter Unger, A2LA, Past Chair
James Bowman, Lockheed Martin
Lynne Neumann, Entela/UILI
Keith Mowry, Underwriters Laboratories
Dan Harper, ISO TAG 176
Others on previous drafts

What are others doing?

- NVLAP
  - Post proposed changes to HB 150 in the Federal Register
  - All labs to comply by mid 2002; next cycle audit review
- A2LA
  - Dependent on “approval” of ISO/IEC FDIS17025
  - Begin auditing mid-2000 (optional, as requested)
  - All labs to comply by 2002
- NIST Quality Policy (included with training materials)
- OWM Plans
  - QM with 17025 text and 17025 database of comments on Internet site
  - Timelines?

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What's *NEW*?

- Scope, organization, focus on clients, uncertainty, traceability
- Section by section identification of what's new
- Summary Minor items
  - System - already in place
  - Documentation
- Summary Major items
  - System - needs work

Scope

- Current ISO/IEC Guide 25
  - routine testing and calibration
  - calibration labs calculate measurement uncertainties
- New ISO 17025
  - includes requirements for sampling, laboratory-developed methods (research)
  - all laboratories must calculate measurement uncertainties

Organization - Sections

- 1 - Scope
- 2 - Normative References
- 3 - Terms and Definitions (ISO 8402, Guide 2, VIM)
- 4 - Management Requirements (Quality System)
- 5 - Technical Requirements
- Annex A - cross references to ISO 9001:1994, 1SO 9002:1994
- Annex B - Guidelines for establishing applications for specific fields
- Bibliography

Section by Section (4 & 5) - What's *New*?

- 1st: Overview of Sections 4 and 5
- Then: Details of Sections 4 and 5

Management Requirements Overview

- 4 - Management Requirements
  - 4.1 Organization and Management
  - 4.2 Quality system
  - NEW – 4.3 Document Control
  - 4.4 Request, tender, and contract review
  - 4.5 Sub-contracting of tests and calibrations
  - 4.6 Purchasing services and supplies
  - NEW – **4.7 Service to the client**
  - 4.8 Complaints

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Management Requirements Overview

- 4 - Management Requirements (cont.)
  - 4.9 Control of non-conforming testing and calibration work
  - 4.10 Corrective Action
  - **4.11 Preventive Action**
  - 4.12 Records
  - 4.13 Internal Audits
  - 4.14 Management Reviews

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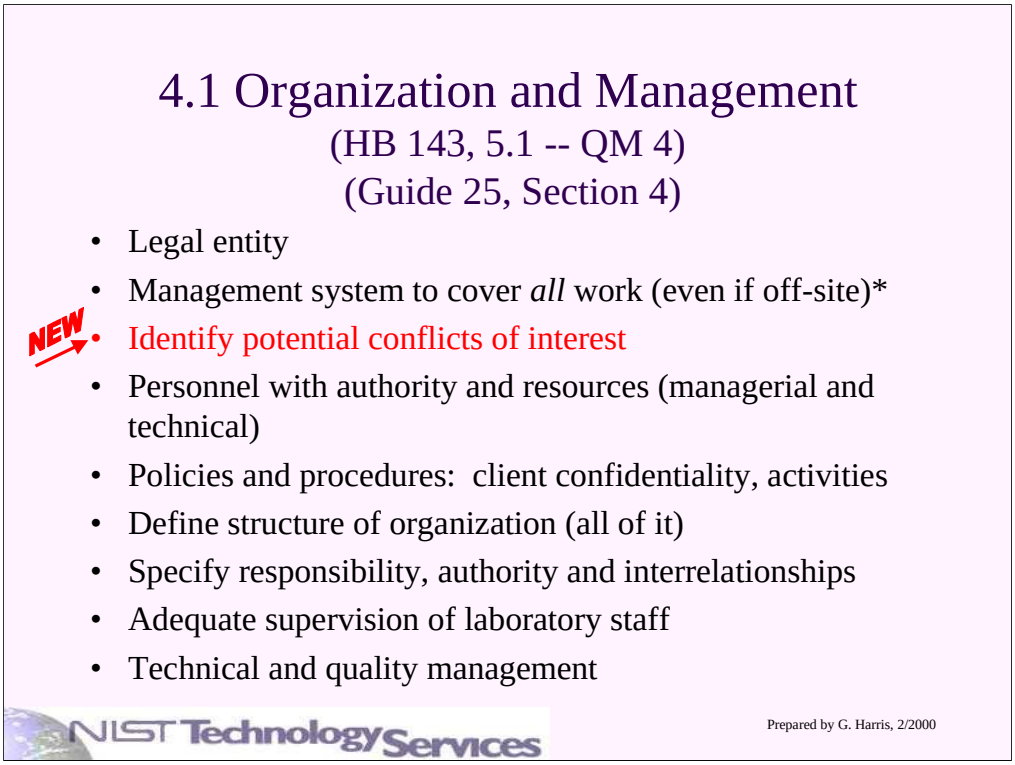
Technical Requirements Overview

- 5 - Technical Requirements
  - 5.1 General
  - 5.2 Personnel
  - 5.3 Accommodation and environmental conditions
  - 5.4 Test and calibration methods and method validation
  - 5.5 Equipment
  - 5.6 Measurement traceability

Technical Requirements Overview

- 5 - Technical Requirements
  - **5.7 Sampling** (NEW)
  - 5.8 Handing of test and calibration items
  - **5.9 Assuring the quality of test and calibration results** (NEW)
  - 5.10 Reporting the Results

BREAK



* weak area for those labs with field or off-site activities. These activities are under the scope of the laboratory responsibilities and must be covered by the quality system.

"4.1.3 The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities." The same requirement is in HB 143, 1997 - section 5.1.1

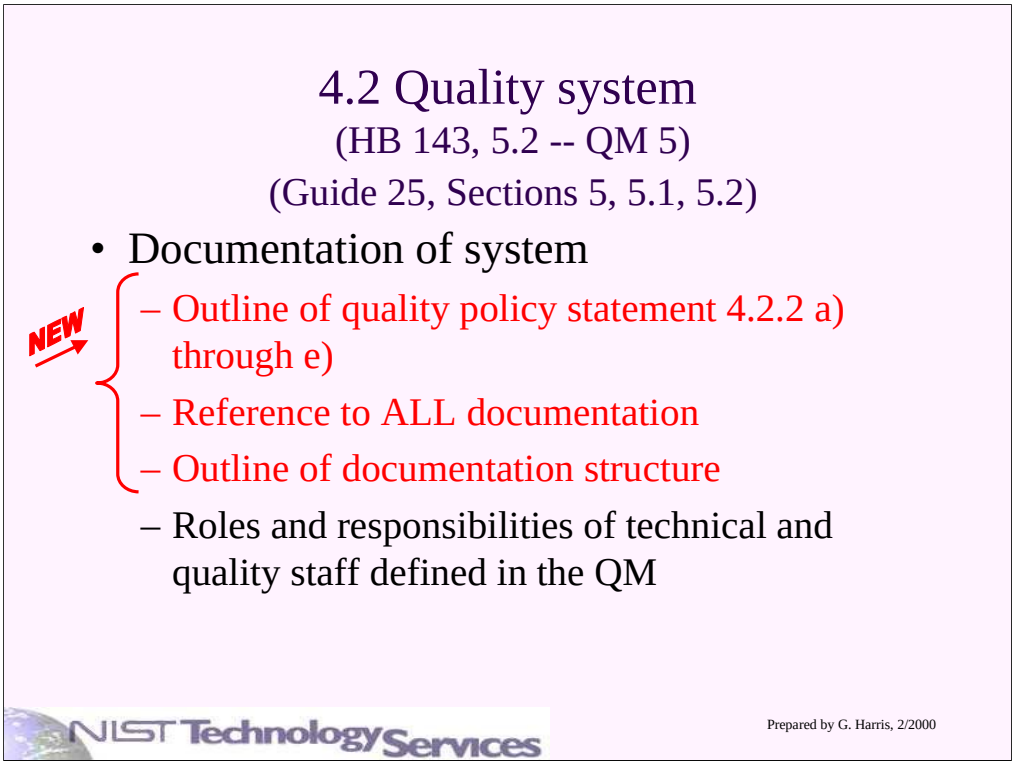
•Current QM and system needs to further expand on "field work". E.g., 5-gallon measures, provers, 25 lb and 50 lb field tests. Meeting requirements of the standard: facilities (deviation from guide, what's ok?), equipment (portable, stationary, stable, secure?), standards and check standards, ongoing verification of traceability and uncertainty, trained staff, training records, deviation from procedures, etc…

•Conflict of interest - partially in QM sections 3.3 and 4.3; but it needs to be defined and not just on an organization chart. Is in HB 143, 5.1.2, b to a limited extent regarding policies to ensure - but NOT to identify potential problems.

•See 4.1.5. - needs some additional documentation for sections b, c, d, e, and f on policies, arrangements, personnel responsibility, and org chart

•OWM NOTE (HB 143, 5.1.2): It is recognized that multifunctions may exist in small laboratories whereby it is difficult or impossible to maintain a distinction between a "technical manager" and a "quality manager." In these cases, OWM technical evaluation and assessment will serve as an independent review as needed or required.

•OWM NOTE (HB 143, 5.1.2): Organizational responsibilities must be defined and identified on an organization chart or similar device. The chart must depict the relation of the laboratory to its parent organization and to other units that report to the same parent. Position descriptions shall be available for each staff member and each shall know his/her responsibilities within the organization.

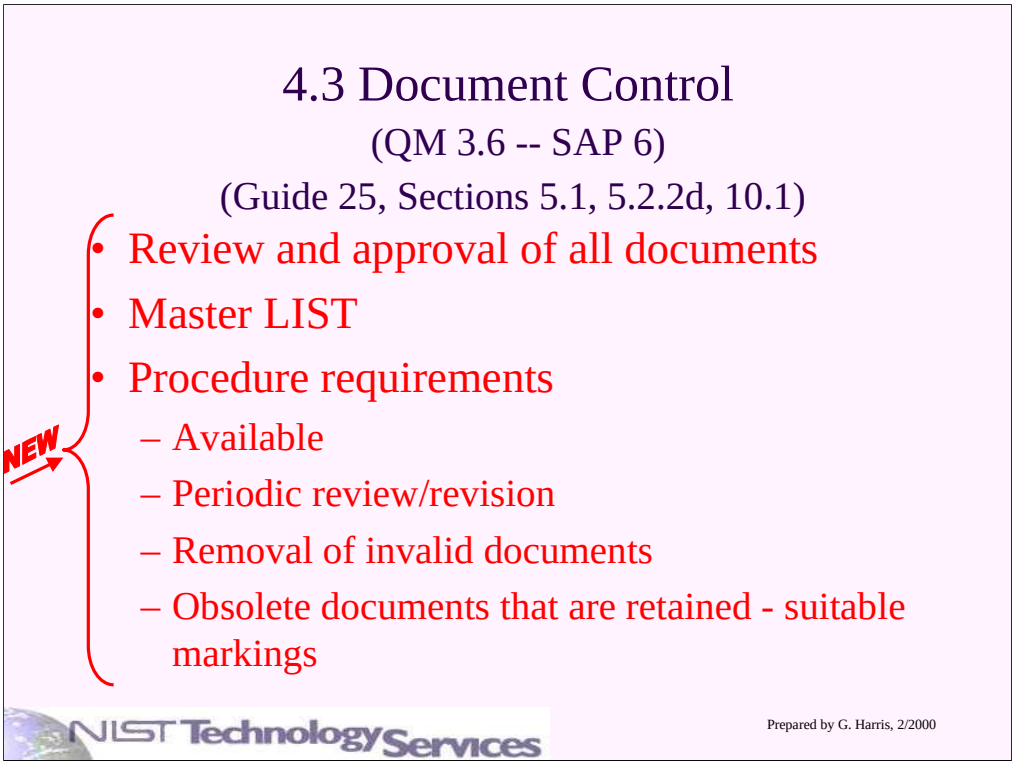


Current quality policy in QM needs to be expanded. Items b, c are weak and the management's commitment is not described in the current policy. Objectives are not listed. D - how do we ensure implementation? A signed statement after training on the quality system? In 3.6.2 of the current QM.

Outline of documentation required:

"4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system."

A list in the QM that indicates "this is what is included in the quality system" index in the appendix or a flow chart outlines it and becomes part of the quality system.



Section 4.3, Documentation control, is expanded from a one line entry (Guide 25) to three major sections with more of the how to's included

- 4.3.1 defines documents to be controlled
- 4.3.2 document approval and issue
- 4.3.3 documentation of changes

Master list of documents in the quality system:

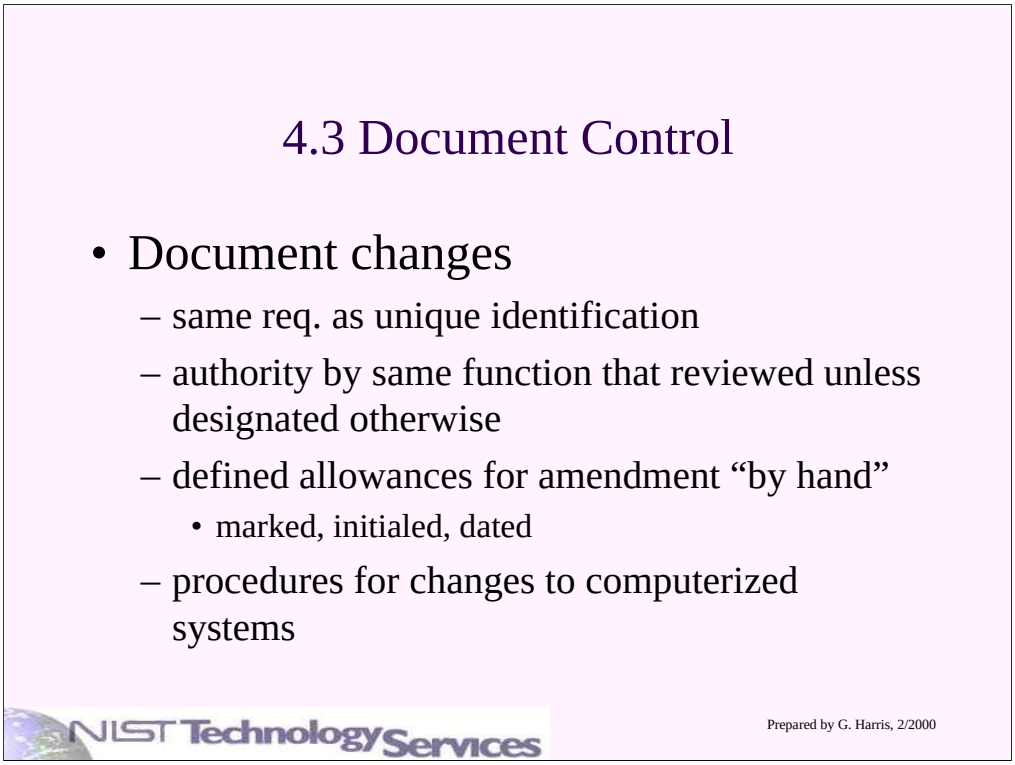
"4.3.2.1 All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and

be readily available to preclude the use of invalid and/or obsolete documents."

Quality Manual section 3.6, Appendix N, SAP 6 but needs additional depth based on the new standard. This was originally included based on ISO 9001 standard and is one area where States are in pretty good shape if they have adopted the QM. It seemed like a "master list" that meets the outlining requirements would help here.

4.3 Document Control

- Unique identification (4.3.2.3)
  - date of issue, revision identification
  - page numbering
  - total number of pages or mark to signify "end"
  - issuing authority

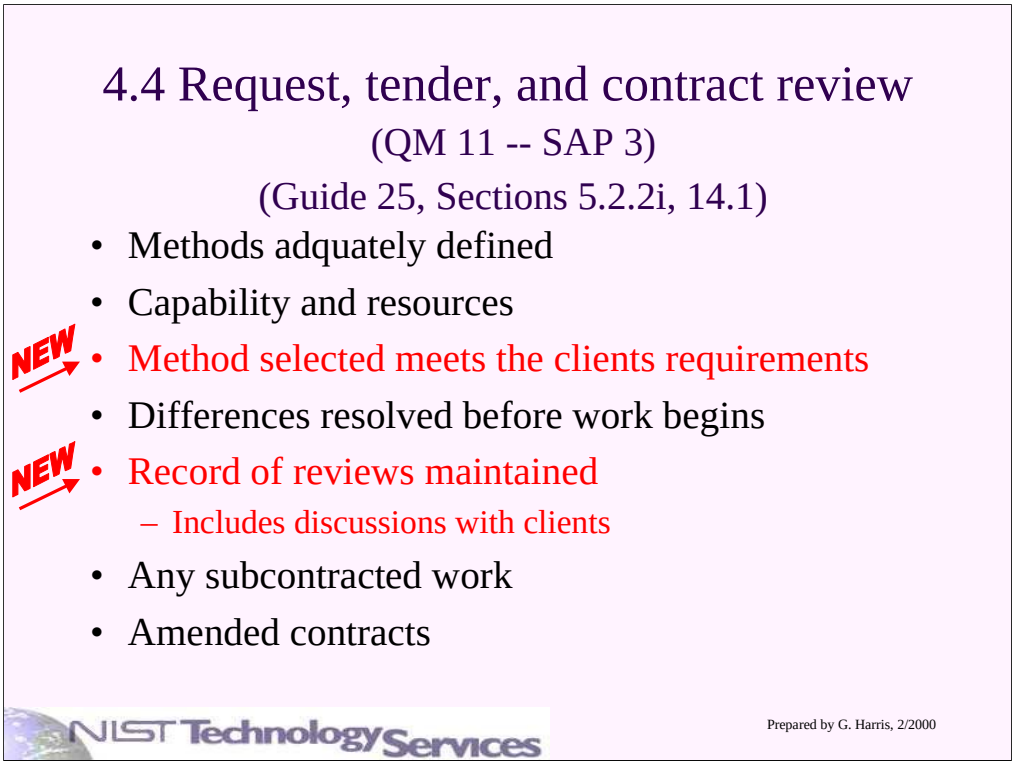


QM 3.6.1 doesn’t deal with changes well. SAP needs to be reviewed and updated.

Need a policy/procedure for computerized documentation systems.

“4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized

systems are made and controlled.”



Section 4.4, Review of request, tender or contract, expanded from one liner (review of new work) in Guide 25 to a major section with detail as to what is expected

- 4.4.1 describes process which lab must follow
- 4.4.2 records
- 4.4.3 subcontracted work
- 4.4.4, 4.4.5 deviations, contract modifications

QM section 11 and SAP 3 address this, but still needs to be enhanced (beefed up). Need definitions of:

"requests"

"tenders"

and "contracts"

Recording pertinent discussions is a current gap in the system. Items that are covered interpreted to include: initial quotes, contact memo, work orders, records of change agreements.

Status calls not applicable unless a "complaint" due to delay of delivery past promised date.

4.5 Sub-contracting of tests and calibrations
(HB 143, 5.11, 6.2.11 -- QM 14)

(Guide 25, Sections 14.1, 14.2)

- Competent subcontractors used
  - compentent: e.g., comply with *this* standard
- NEW Advise and gain approval of the client (preferably in writing)
- Responsible for subcontractors work, except where required by client or regulation
- Maintain register of all subcontractors used along with evidence of compliance

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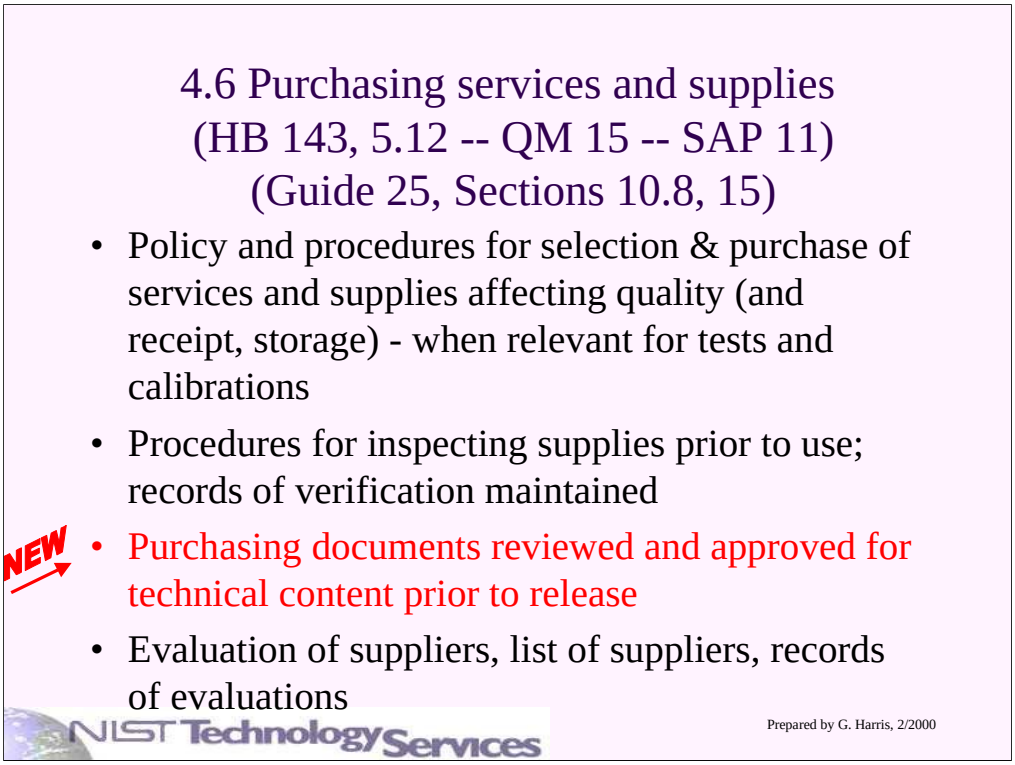
Few labs are subcontracting.

But, State labs are often subcontractors for others….. Implications. State labs will need to comply with 17025 to meet the others' requirements of this section when State labs are used for subcontracting.

Modification of the verification letter is a move in the right direction for those labs who haven't sought NVLAP accreditation yet.



Process for reviewing purchasing documents prior to release and govt/admin systems?

"4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release."

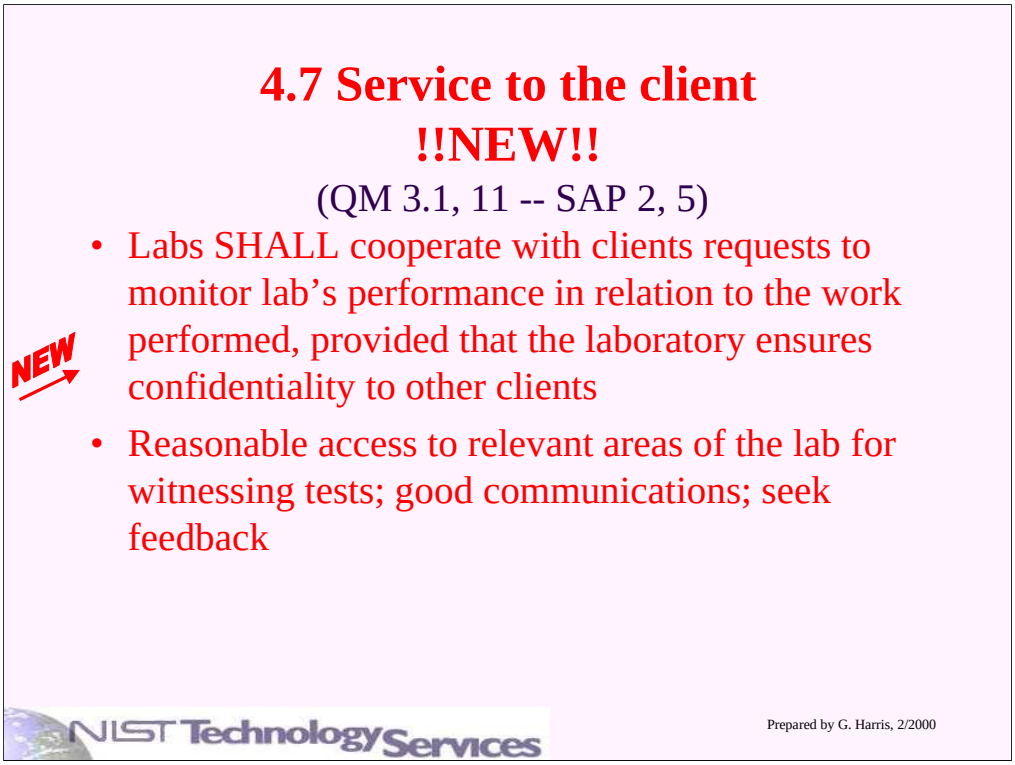
Most of us in government, don't have this option, unless we define it as release from our area…same problem at NIST.

Perhaps maintain a list of what is relevant and what about that item needs to be checked when it can affect the quality of the work.

Quality of items should be addressed in the procedures (HB 145) as they get updated to address this issue.

"Label checks" are acceptable actions to take in some cases.

Need records of evaluations and lists of those approved. Lab determines what is critical and how the evaluation is completed. Customer evaluation forms in purchasing department would allow feedback to company are helpful if the supplies don't meet acceptable quality limits.



Nothing in the current QM addresses the level of detail specified. New SAP needed. HB 143: 5.2, 5.8.2; QM: 3.1. 11 (not specific); SAP: 3.3.1, 9.3.2, 9.4.2, 2, and 5

4.7 Service to the client

The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.

NOTE 1 Such cooperation may include:

a) providing the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the client for verification purposes…..

This section can probably be used both ways:

1. To allow controlled access.

To allow monitoring in the spirit of the standard to cooperate with customers.

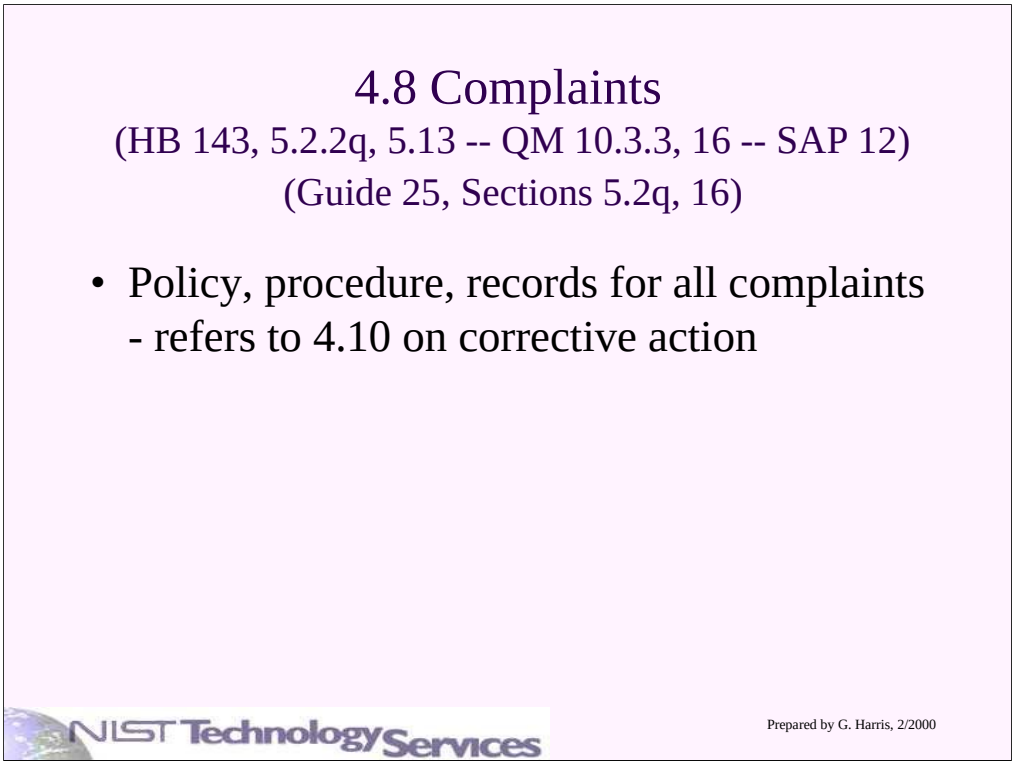
To demonstrate quality and gain credibility with the customer.

2. To disallow controlled access.

Security and access of standards and equipment.

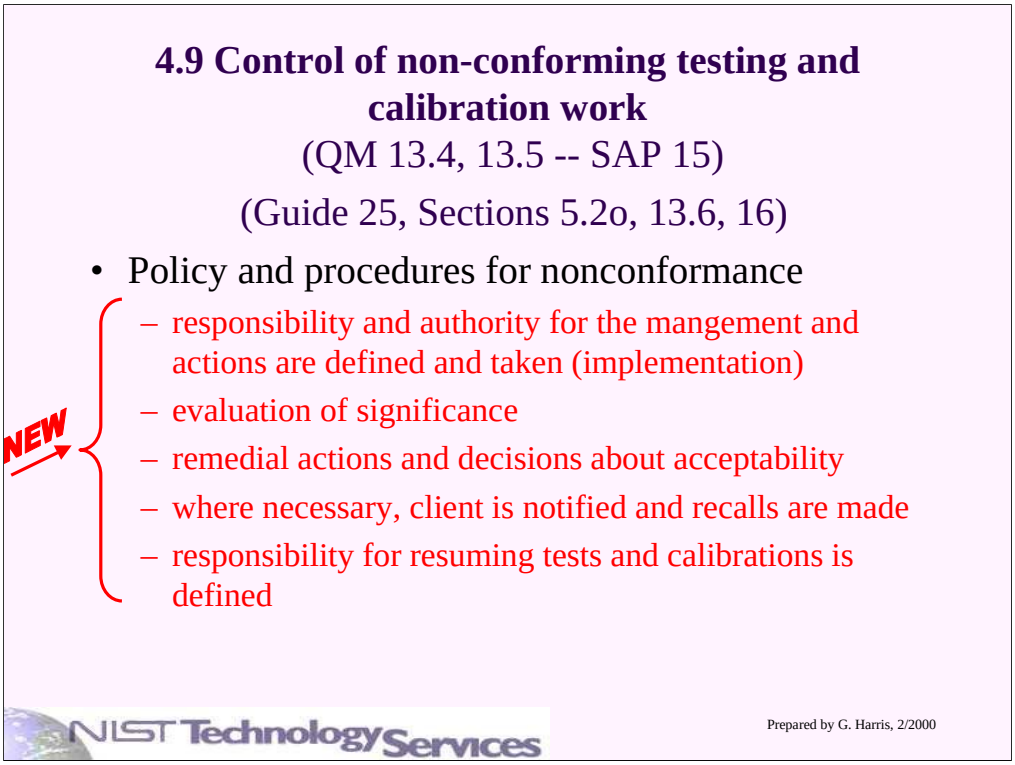
Impact on environmental controls.

Other customer equipment or standards in the lab and violation of confidentiality clause.



How many labs have actually implemented a complaints policy, procedure and keep records???

Need policy and procedure reviewed.



Section 4.9, Control of nonconforming testing and/or calibration work, expanded from one liner in Guide 25 to a major section with detail

- •policy and procedures required
- •evaluation of significance of nonconformance
- •remedial actions taken
- •client notified, work recalled

Section 4.9 e - authorizing the resumption of work after nonconformity (biggest gap)

"4.9 Control of nonconforming testing and/or calibration work

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that: …..

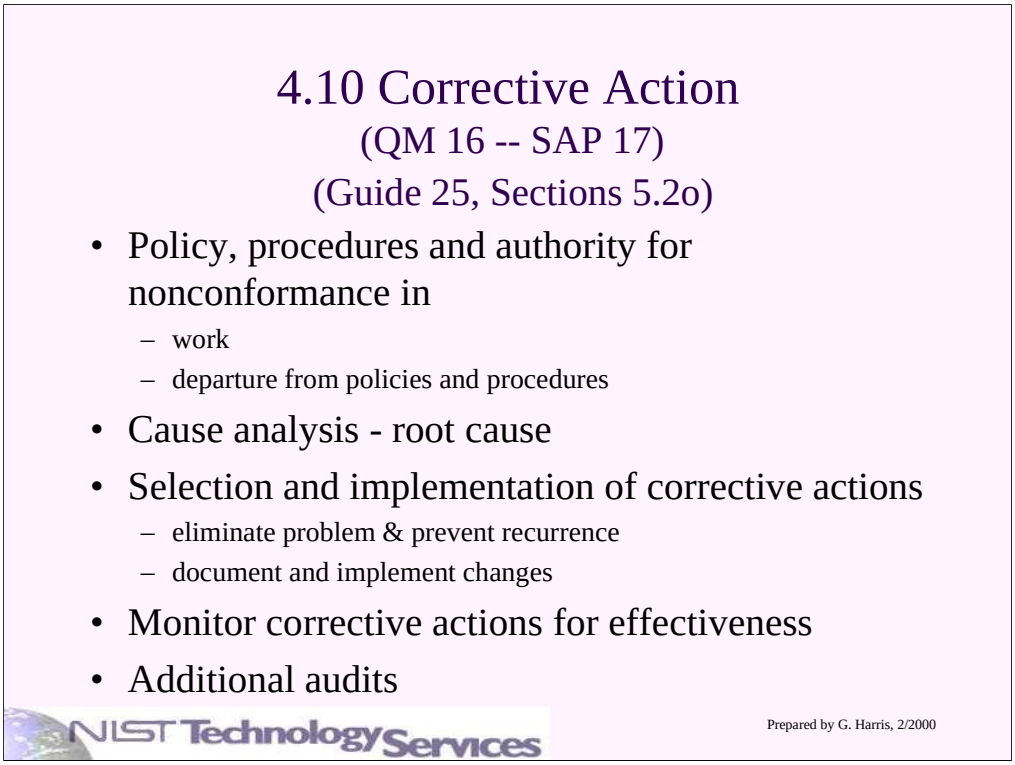
e) the responsibility for authorizing the resumption of work is defined."

4.9.1: QM 16.2, SAP 12, 4.4, 4.6, 15

4.9.1a: QM 5.3.4, 16.2, 4.3.3. Need to modify to address what happens if it isn't found during an audit.

4.9.1d, SAP 17 is recall procedure

SAP 4.4.4 need to include corrective action for not following your own procedures



Corrective Action: Identify AFTER the fact to prevent recurrence (clean up mess)

Preventive Action: Identify potential possibilities that haven't occurred

Section 4.10, Corrective action, presents the concept of Cause Analysis, identification of potential corrective actions, monitoring the results of corrective actions, and special audits

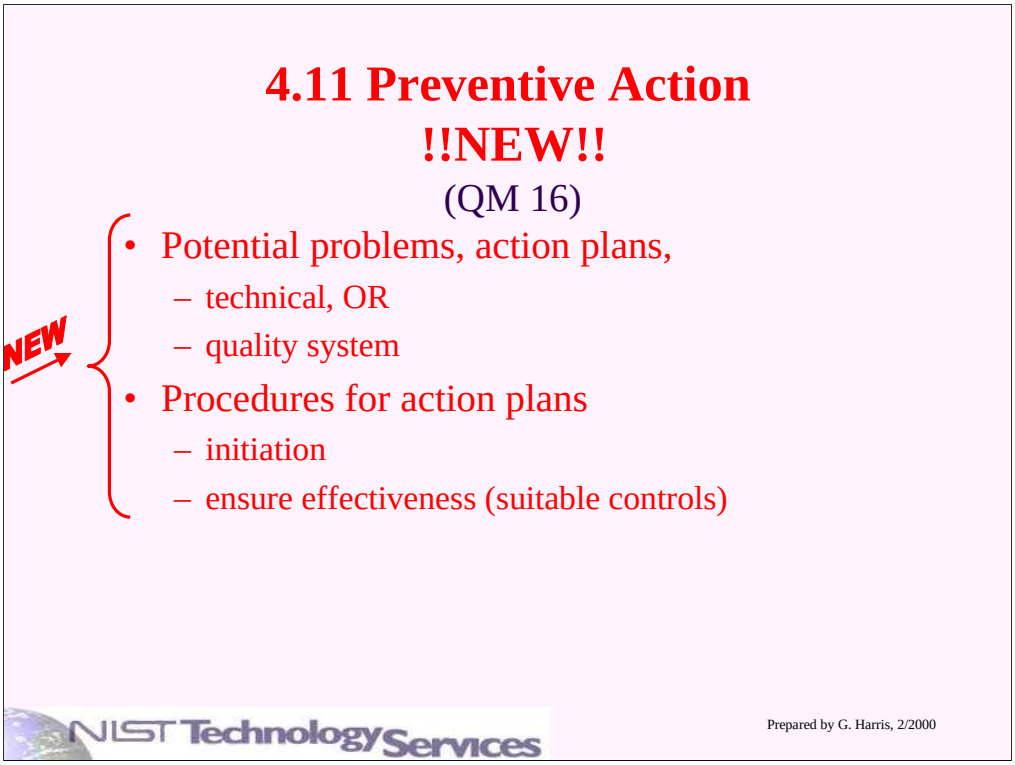
- Root cause investigation
- Implementation of actions
- Monitoring, additional audits

Monitoring of corrective actions 4.10.4

"4.10.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective."

Add section to SAP 12 to comply with 4.3.4; add a section to indicate that lab monitors for effective corrective action.



Section 4.11, Preventive Action, introduces a new concept from ISO 9000. This will take a bit of education for the labs to get in compliance. Proaction versus reaction, trend analysis, risk assessment, etc.

- Opportunities for improvement
- Action plans
- Assessment of effectiveness

Is already in the Quality Manual Template, Section 16 but still needs some work. Add sections on management review and records, add section on effective corrective/preventive action, add special audits; see MN SAPs.

"4.11 Preventive action

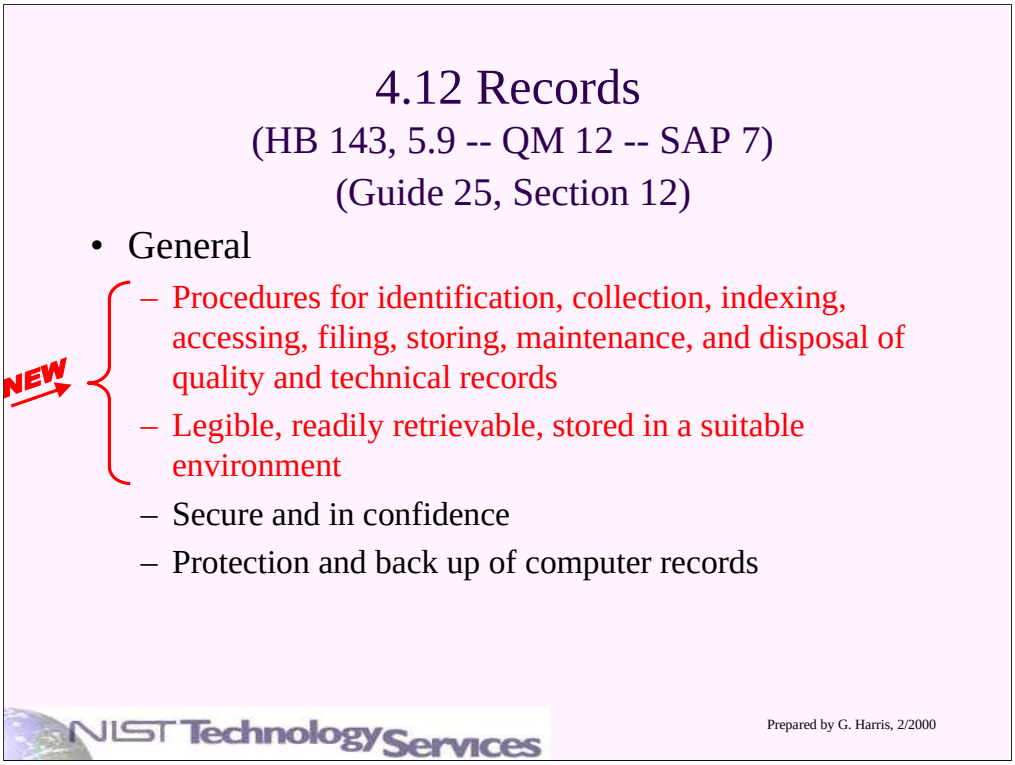
4.11.1 Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented

and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.

4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

NOTE 1 Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results."



Section 4.12, Records, adds requirement to identify and properly retain quality records as well as technical records required by Guide 25

- Procedures required
- Security
- Backup

4.12 Records

- Retain records of original observations, derived data, information for audit trail, calibration records, staff records, etc - sufficient information to repeat calibration
- Identify personnel involved
- Observations recorded at the time they are made
- Mistakes crossed out, NOT erased, made illegible or deleted, and correct value entered along side - signed and initialled
  - electronic means for doing so as well!

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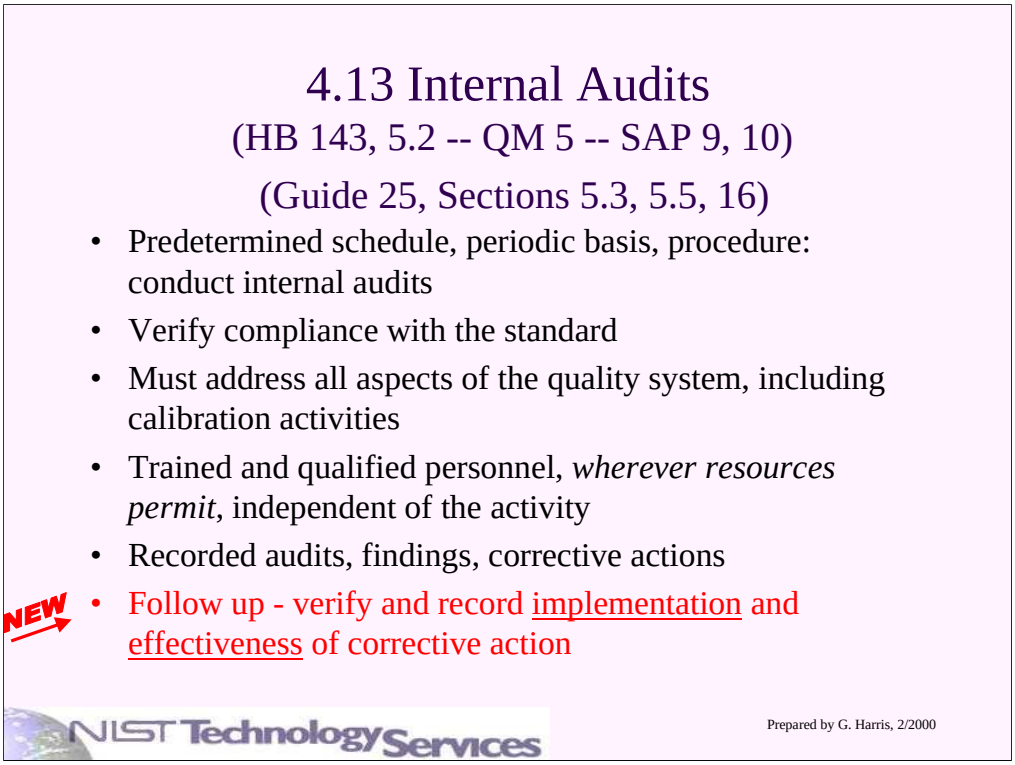
Section 4.12, Records, adds requirement to identify and properly retain quality records as well as technical records required by Guide 25

- Procedures required
- Security
- Backup

QM section 12.1 and Basic seminar addresses handling of mistakes, erasures, legibility, etc.

How will we handle it electronically? Good question.

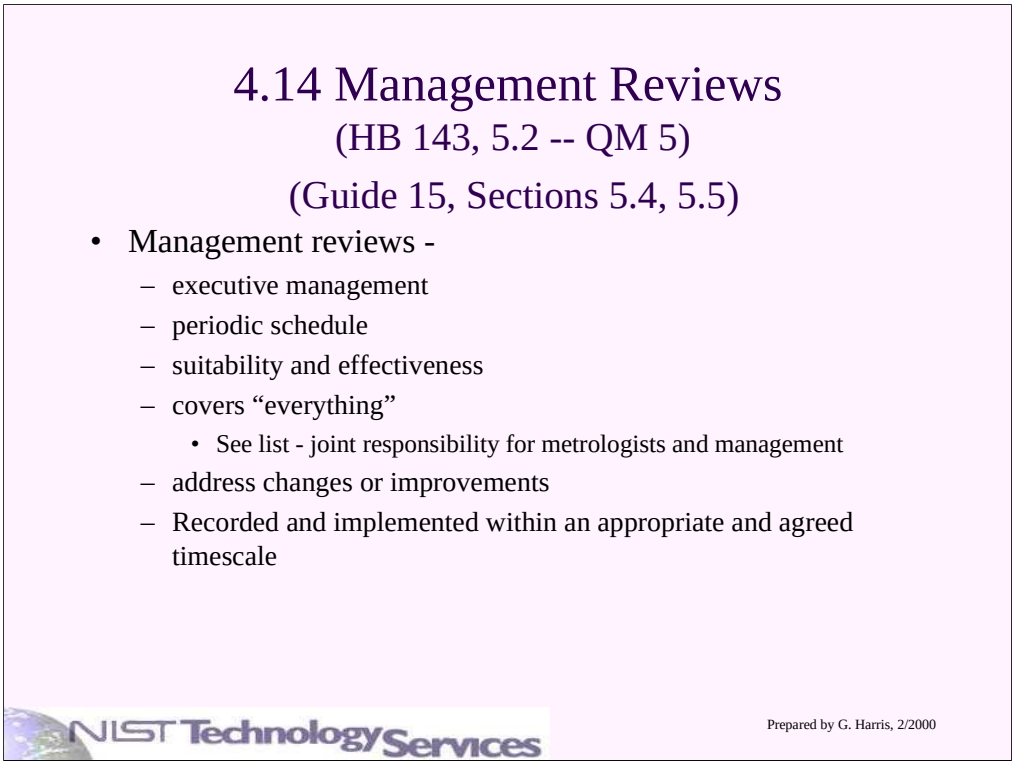


4.13.4 - follow up audit activities to measure implementation and effectiveness:

"4.13.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken."

Need a system in place to make sure it gets scheduled and followed up. Notebook or tickler file to track all corrective actions which can then be used in the next internal audit.

Effectiveness and implementation are NOT in the current QM or system.



Prescriptive planning on the part of management, App C, part 1 doesn’t have enough detail and isn’t often PLANNED although some are using it for evaluation. It needs a numbering system to correlate to the requirements of the standard and a better way to show comments ARE required. Need addition to handle corrective actions suggested/required by NIST or other external audit as well.

“**4.14.1** In accordance with a predetermined schedule and procedure, the laboratory’s executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

•see actual text

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans

for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

4.14.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.”

OWM NOTE (HB 143, 5.2.4): Appendix C contains an "Internal Assessment and Management Review" form that is to be used for this activity and is to be submitted annually or as circumstances change in the laboratory. GH note: when performed completely, they are pretty good and are close to compliance with the exception of the new criteria to be reviewed.

5.1 General

(QM 5.2, 6.4, OWM Training -- GMP 12, SAP 16, SOP 29)

- Many factors impact correctness and reliability of tests and calibrations….
  - See list
- Extent that factors affect uncertainty shall be taken into account in
  - test procedures
  - training/qualification of personnel
  - selection and calibration of equipment

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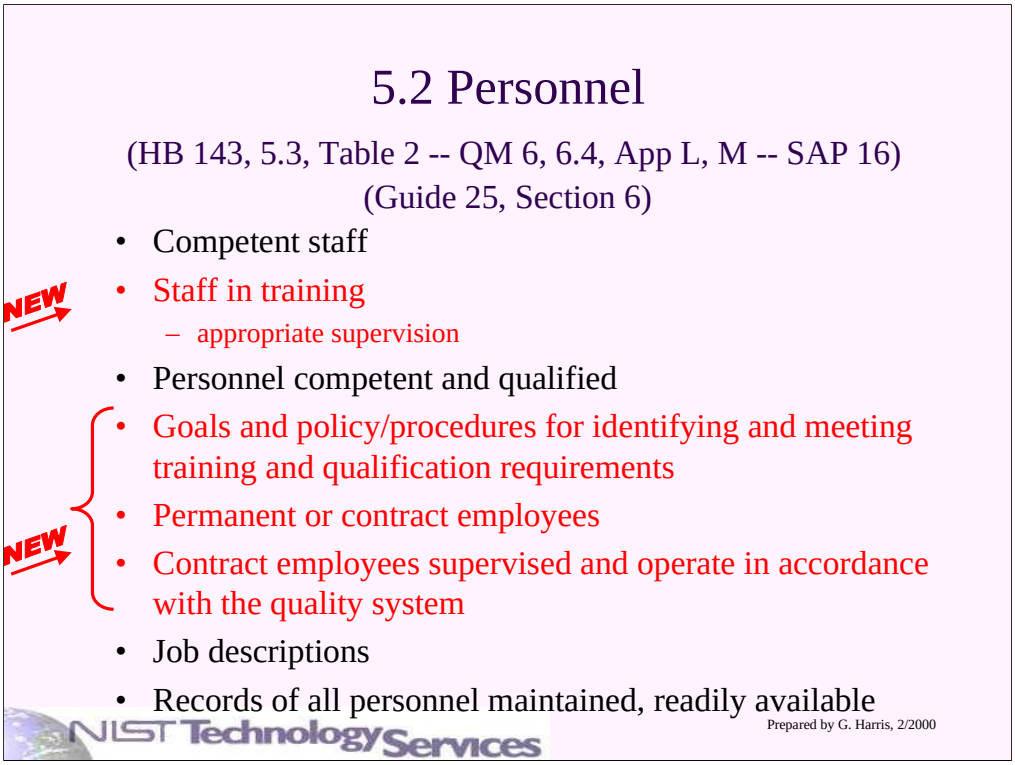


Section 5.2, Personnel, expanded considerably from two sentences in Guide 25 to 5 paragraphs with more detail

- Management responsibilities
- Policies and procedures to identify training needs
- Supervision of staff undergoing training

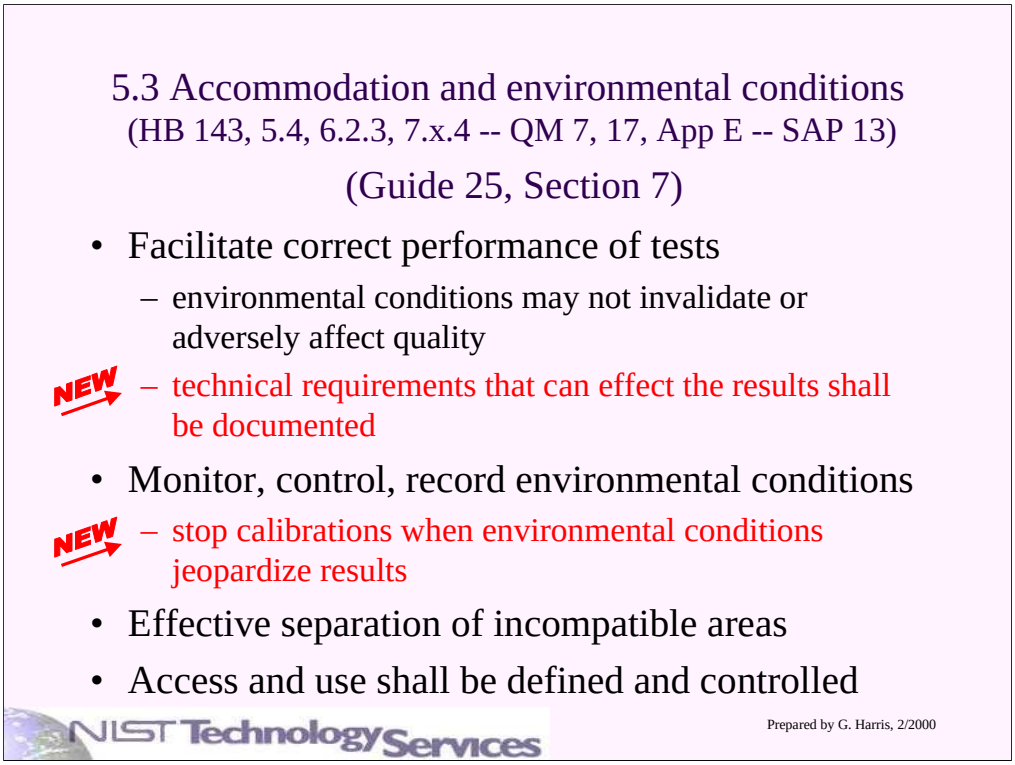
5.2.2, Policy and procedure for identifying training needs

"5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the laboratory."

OWM NOTE (HB 143, 5.3): The NIST Office of Weights and Measures provides training to State legal metrology laboratories. State metrologists are required to complete the appropriate level of training as indicated in Table 2 (p. 36), for the laboratory to be recognized at designated levels. Information regarding the training program is maintained in the Office of Weights and Measures.

*Affects field staff assigned PT to the lab: must comply with quality system and meet quality system training requirements…..

*5.2.1 Note 1 - personnel certification: hoist, forklift, dosimetry handling



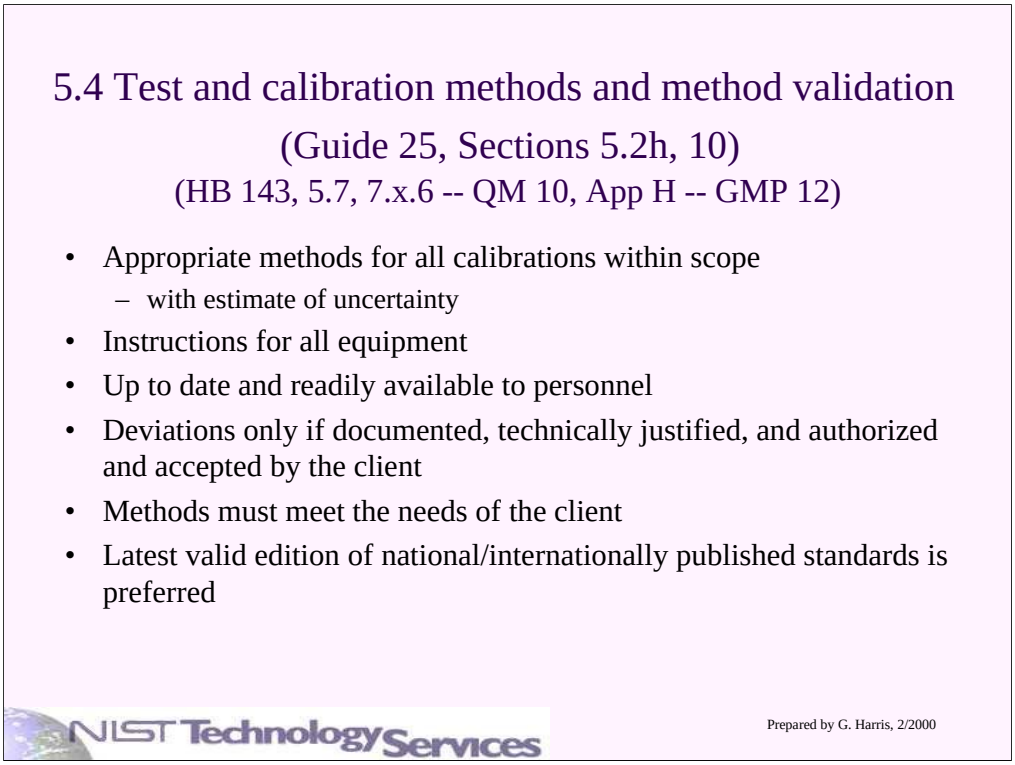
OWM NOTE (HB 143, 5.4): Section 7 of this Handbook contains specific technical requirements for various measurement parameters that will be used for additional guidance in laboratory assessments.

Affects off-site facilities as well:

"5.3.1 ... Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. … Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations."

QM spells out requirements according to section 7 of HB 143.



Section 5.4, Test and calibration methods and method validation, adds sampling but is not significantly different from Guide 25 requirements. Detail on validation of test methods, and estimation of measurement uncertainty is also provided.

•Testing laboratories are expected to be able to estimate uncertainty when appropriate

Validation of methods is weak:

"5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use."

OWM NOTE (HB 143, 5.7.8): The NIST Office of Weights and Measures maintains NIST Handbook 145, Handbook for the Quality Assurance of Metrological Measurements. States must reference this handbook and use it for all applicable measurement procedures unless data or other evidence is available to support acceptable results using another procedure. Other procedures must be submitted to OWM for review and approval by the NIST Office of Weights and Measures. Use of uniform procedures is critical for maintaining the integrity of the legal measurement system.

5.4 Test and calibration methods and method validation

5.4.6 Estimation of Uncertainty
(QM 9.4, App I, SOP 29, 30)

- Laboratory developed methods must be
  - appropriate for intended use and
  - validated
  - part of a planned activity assigned to personnel with qualifications and resources
- Non-standard methods subject to agreement with the client and be validated
- Procedure requirements/contents
- Validation: procedures, records, evidence, meet client needs
- Estimation of uncertainty required - all components of importance considered
- Control of data (validated software, protection of data)

NEW

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Procedure “contents” listed.

Validation requirements listed.

Uncertainty - references ISO Guide.

Lots of notes.

5.5 Equipment

(HB 143, 5.5, 7.x.5 -- QM 8, App F, G -- SAP 4)

(Guide 25, Section 8)

- Lab with all equipment required for the correct performance of the calibrations
  - for equipment outside permanent control, must meet requirements of the standard
- Equipment and software capable of achieving accuracy needed
- Authorized personnel; up to date instructions
- Unique identification
- List of records for each piece of equipment

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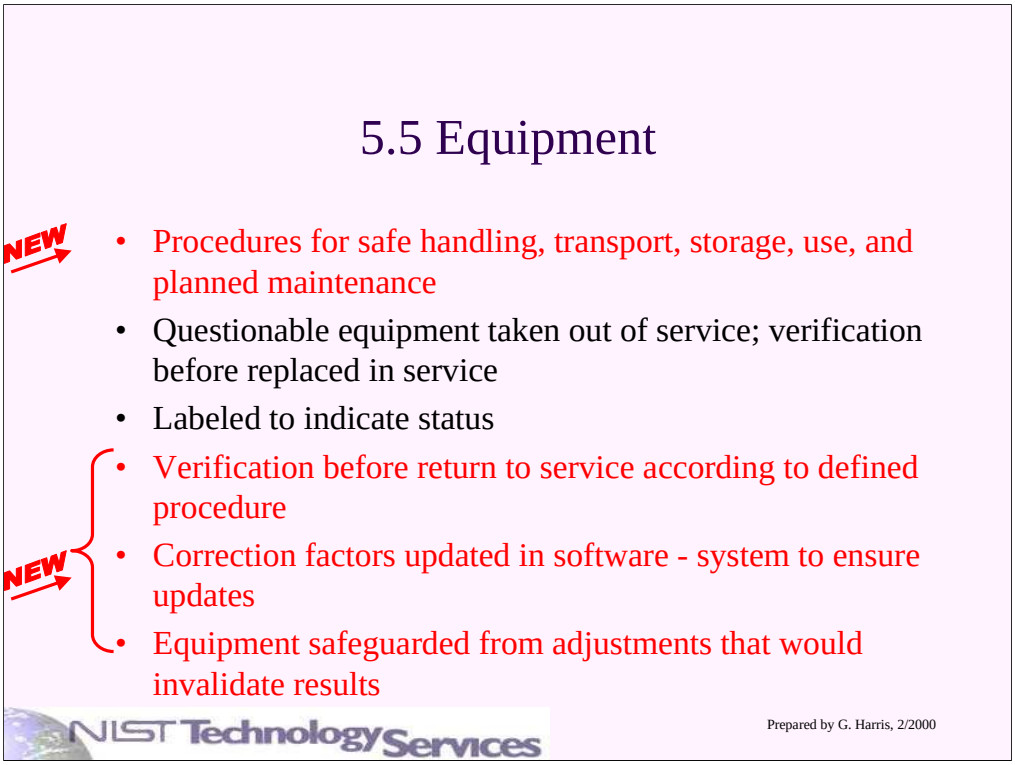
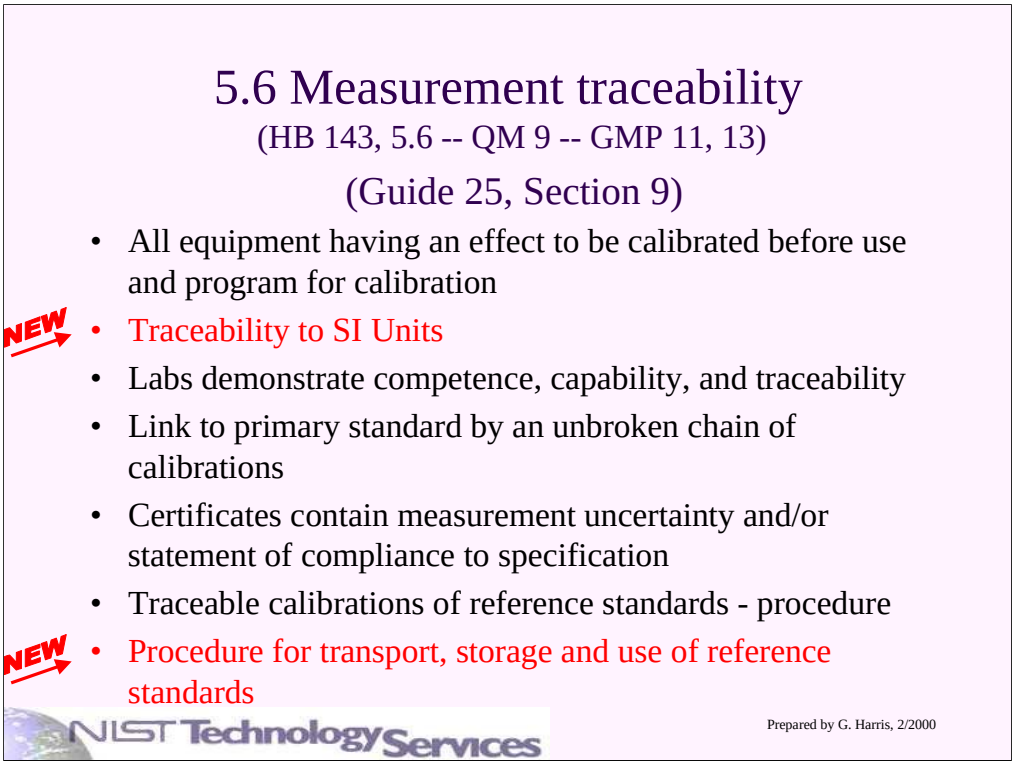
OWM NOTE (HB 143, 5.5.4): The quality manual template contains a chart to list of equipment and its current performance evaluation. This information will be requested during on-site assessments, and the chart may be requested annually for review with measurement control documents.



Need procedures for returning equipment to service.

Need system for updating software corrections when used.



Concern about traceability to SI Units:

"5.6.2.1.1 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités)."

HB 130 Section 2. Systems of Weights and Measures

The International System of Units (SI)[Note 2, see page] and the system of weights and measures in customary use in the United States are jointly recognized, and either one or both of these systems shall be used for all commercial purposes in the State. The definitions of basic units of weight and measure, the tables of weight and measure, and weights and measures equivalents as published by the National Institute of Standards and Technology are recognized and shall govern weighing and measuring equipment and transactions in the State. (Amended 1993)

OWM NOTE (HB 143, 5.6.5): A competent body will generally be interpreted as NIST, or a State laboratory with a Certificate of Traceability, or other laboratory for formal accreditation from a recognized accreditation body.

•NVLAP and A2LA traceability policies - included with training materials. Verification letter will be revised (included with training materials)

•Competence defined by compliance to the standard.

5.7 Sampling

(Guide 25, Sections 10.2, 10.5)

- Sampling plan and procedures for sampling
- Deviations for customer require detailed records
- Procedures for recording relevant data and operations related to sampling

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Section 5.7, Sampling, is a new section which requires a sampling plan and documentation of results

- •Applies when sampling is done prior to testing or calibration
- •Proper statistical methods must be used
- •Procedures for generation/maintenance of records

CA testing of field standards is sampling. Is it under the scope of accreditation or recognition? Probably since it is used for legal metrology applications.

5.8 Handing of test and calibration items

(HB 143, 5.8, 7.x.7 or 7.x.8 -- QM 11, 17 -- SAP 4, 14)

(Guide 25, Sections 5.2k, 11)

- Procedures for transport, receipt, handling, protection, retention, disposal
- System for uniquely identifying item while in the laboratory
- Any deviations recorded; consultation with client
- Procedures and facilities to avoid damage to item (protect integrity while in custody)
- Record of environmental conditions

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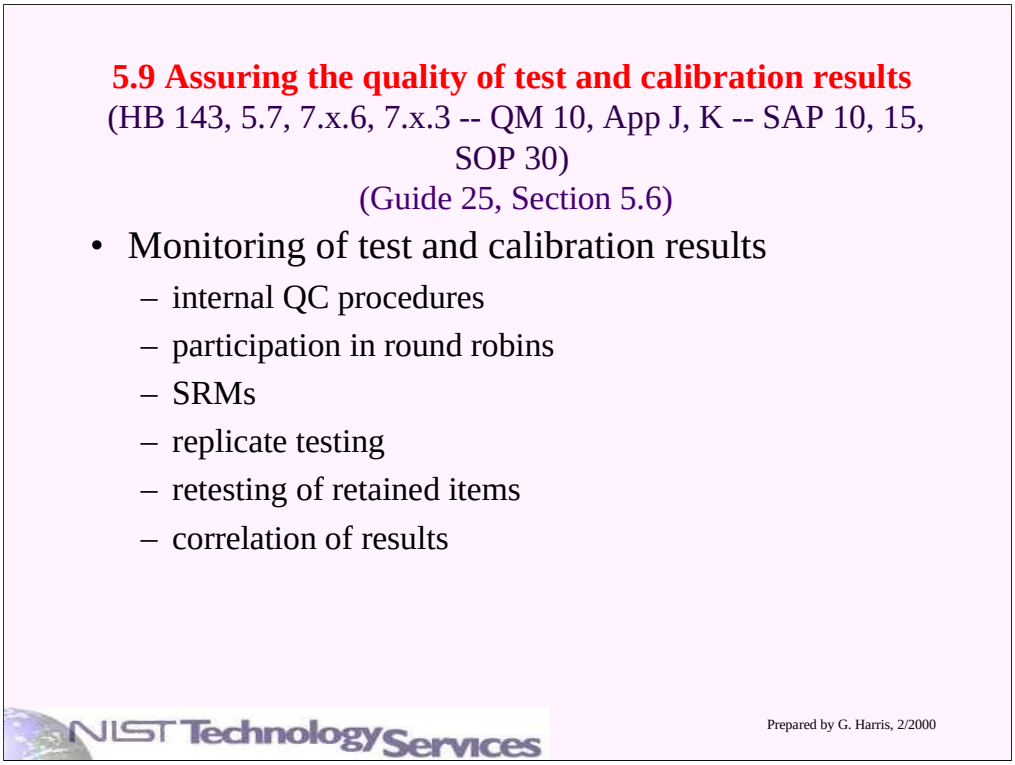
Not much change from previous guidelines or procedures.

Except: recording discussions with clients:

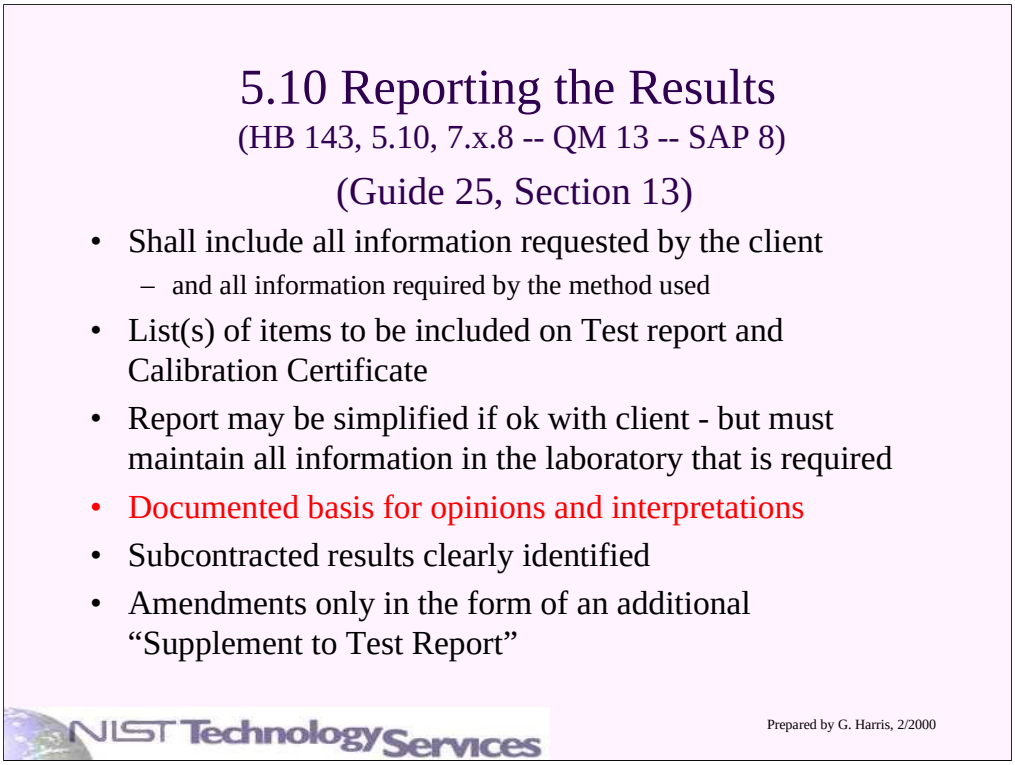
"5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion."



Section 5.9, Assuring the quality of test and calibration results, is a new section based on the section in ANSI/NCSL Z540-1 (5.6 a through e) that speaks of ways to ensure quality of measurements

OWM NOTE (HB 143, 5.2.6): The laboratory shall maintain a list of control charts or surveillance activities maintained by the laboratory. Measurement control requirements must be in place for each measurement service provided by the laboratory. The quality manual template contains forms that may be used by the laboratory to list control charts, surveillance activities, and proficiency tests. This documentation must be available during on-site assessments and submitted to the NIST Office of Weights and Measures as requested.

With previous system, plus PMAP, plus round robins, we should be in good shape on this section. But, it needs to be included in internal audit and management review….planned and reviewed.



Section 5.10, Reporting the results, Separates testing and calibration, adds sampling, opinions and interpretations. Not significantly different from Guide 25 plus ANSI/NCSL Z540 additions in areas of traceability and uncertainty

•Basis for opinions and interpretations must be documented and clearly identifiable in the test report

•All information… how much is too much???

"5.10.1 General - second Paragraph:

The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4."

•Notes in database regarding requirement of k factors are covered by 5.4.6.3, Note 3.

•5.10.4.2 - statement of compliance (E 617 requires all specifications, values, and uncertainty to tolerance ratios to be met to state "in compliance")

•5.10.4.3 - before/after values, if available (as received standards)

•5.10.4.4 calibration intervals specified only if regulatory or agreed to or requested by the client

•5.10.5 e.g. FACT - weights were found with "strings" attached, OPINION/INTERPRETATION - strings are inappropriate and invalidate requirements of the standard

•5.10.6 issue reports to subcontracting lab - they are obligated to identify subcontracted portion on their reports

•5.10.8 reporting format (E.g., R 111), HB 143 Section 7 includes additional items that are standard to be reported

•5.10.9, SAP 8 needs wording "supplemental"

LUNCH

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Summary "*Minor*" items

- *Minor* = System already in place
- Documentation - P&P (policies and procedures)
- Working Group Assessment
  - Outline or flow charts of quality system documentation
  - Clean/refine QM
    - policy
    - improve reference to SAPs
    - streamline # locations with repetition
    - reference to procedures (SOPs, GMPs, etc.)
  - Word indexing to allow search by keywords

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Summary "*Major*" items

- *Major* = System needs work
- Working Group Assessment - Top Items
  - Management Review***
  - Service to the Client
  - Documenting customer/client contact/communications
  - Handling electronic errors
  - Sampling

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What's the *IMPACT*?

- Additional documentation
  - if laboratory system is already in place, minimal updating will be needed
  - if laboratory system is NOT in place - deadline is FAST approaching!
    - July 1, 2001 for HB 143, 1997 (and 2002 Recognition cycle for next phase)
- Management review - gaining manager/director buy-in and support
  - Expand Appendix C, Part 1 for internal audit and management review

What's *NEXT*?

- Action Items
  - Revise "verification letters" to match NVLAP and A2LA "traceability policies" as much as possible - 2001 cycle
  - Refine and update Quality Manuals, SAPs (SOPs, GLPs, GMPs, etc)
    - NIST IR 5802 with 17025 notes is available for downloading at: http://www.nist.gov/owm under laboratory metrology, quality systems
  - Review and update HB 143
    - Section 5/6 (now is Z 540-1-1994) → ISO 17025
    - Section 7, match numbering system and update where needed
  - Training
    - Labs - 2000 RMAPs - March to October
    - Directors
  - Labs - update systems
  - Labs train staff on changes and lab systems
  - Technical audit checklist - by Section 7, by SOP methods developed
  - Cross Reference/index needed

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Case Studies

1. Off-site calibrations of test measures, provers, 25-lb and 50-lb field standards, weight carts, wheel load weighers (scope of recognition, compliance to the standards)
2. Review of selected calibration reports (many reports are still inadequate, especially for “tolerance testing”)
3. Customer would like to watch your calibration (customer service focus vs security/access to the lab)
4. PMAP/Measurement Assurance Chart shows readings out of control (corrective/preventive action focus)
5. Laboratory Management signing off on submission to NIST (inadequate management review and what should be included)

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Break into 5 groups to review the standard. Find all applicable sections of the standard like we did for the 17025 Training. Make a list (flip chart) in each group of what is required and note* which items are already a part of the system. Suggest recommendations to deal with any gaps noted.

Each case study is more thoroughly described in an attachment to the presentation materials.

Select a spokesperson for the group to present to the entire group after the break.

BREAK

Case Studies

- Group presentations
- Questions and answers

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One person from each group presents the summary of the case study.

Q&A time for the case studies.

Summary & Review

- History of Quality Standards for the State Labs
  - ?
- What's *NEW*?
  - ?
- What's the *IMPACT*?
  - ?
- What's *NEXT*?
  - ?
- Case Studies
  - Lessons Learned?

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Track major review items for each section on a flip chart to get an idea of what everyone has retained from the sessions.

Q&A

- Are there other standards we should consider while updating?
  - E.g., Baldridge criteria
    - Leadership
    - Strategic Planning?
    - Customer and Market Focus*
    - Information and Analysis
    - Human Resource Focus?
    - Process Management?
    - Business Results
- http://www.nist.gov/owm, see Laboratory Metrology, Quality System for all downloadable files
- Questions?

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Customer and Market Focus - latest version of 17025 includes customer focus, a key factor of Baldridge criteria

Business performance - includes effectiveness results

Leadership - includes performance reviews of the organization and systems

Many State Quality systems modeled after Baldridge…NIST encouraging it's use in laboratories. Ideas?